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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,549	03/07/2001	Jorg Priewe	SCH 1705	3734

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EXAMINER

WARE, TODD

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,549

Applicant(s)

PRIEWE ET AL.

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-14 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Receipt of response and amendment filed 3-14-03 is acknowledged. Claims 20-21 have been added as requested. Claims 1-2, 4-14, and 16-21 are pending.

Election/Restrictions

1. Newly submitted claims 20-21 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions of claims 1-2, 4-14, and 16-19 and claims 20-21 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, such as for the sustained release of pharmaceutical agents (see Goldstein et al, US 6,143,037)..

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-21 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

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2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. **Claims 1-2, 4-5, 8-10, 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al (6,143,037; hereafter '037).**

5. '037 teaches medical devices such as stents coated with a butyl ester cyanoacrylate polymer where the polymer is applied to the stents by dipping the medical device in a solution of the polymer. '037 also discloses that proteins are applied to the device.

Response to Arguments

6. Applicant's arguments filed 3-14-03 have been fully considered but they are not persuasive. Applicant argues that '037 does not render the instant claims obvious because it teaches a genus of the instant species and lacks direction or reasons for

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making selection of stents and polymer coatings (i.e. it discloses a laundry list of medical devices and polymers). Determination of obviousness is on the basis that the size of the genus is small (23 medical devices listed in column 31, lines 25-47 and 7 classes of polymers listing 4 specific polymers as coatings). It is noted that the mere fact that a prior art genus contains a small number of members does not create a per se rule of obviousness. Some motivation to select the claimed species or subgenus must be taught by the prior art. *In re Baird*, 16 F.3d at 383, 29 USPQ2d 1550 (CAFC 1994). In this determination, it is first noted that '037 teaches the same medical devices (stents) and polymers (n-butyl cyanoacrylate) and therefore teaches the same structural similarity and there is no teaching away from one species for another. Accordingly, there is expectation that the claimed subject matter will function in an equivalent manner to the genus. Furthermore, '037 teaches that the genus (medical device/stent and biodegradable polymers) have similar properties and uses. In *In re Dillon*, 919 F.2d at 697, 16 USPQ2d at 1897, the CAFC established that if the claimed invention and the structurally similar prior art species share any useful property, that will generally be sufficient to motivate an artisan of ordinary skill to make the claimed species. Furthermore, while if the technology is unpredictable, it is less likely that structurally similar species will render a claimed species obvious because it may not be reasonable to infer that they would share similar properties as in *In re May*, 574 F.2d 1082, 1094, 197 USPQ 601, 611 (CCPA 1978). However, the instant technology is predictable. It is also noted that while the instant claims are directed toward stents, stents are only enumerated on pages 5 and 6 of the instant 21 page specification. The remainder of

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the specification teaches coating the genus "medical implants." Therefore, no evidence for the criticality of stents has been provided. Accordingly, the evidence as a whole supports a *prima facie* case that the claimed invention would have been obvious to one of ordinary skill in the relevant art at the time the invention was made.

Applicant further argues that '037 fails to teach a softener or nonionic surfactant. This argument is not found persuasive. Column 14, lines 20-41 teach inclusion of poloxamers as emulsifying agents in the taught coatings.

7. Claim 6-7, 11, and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al (6,143,037; hereafter '037) in view of Clark et al (6,143,352; hereafter '352).

8. '037 teaches medical devices such as stents coated with a butyl ester cyanoacrylate polymer where the polymer is applied to the medical device by dipping the medical device in a solution of the polymer. '037 also discloses that proteins are applied to the device.

9. '352 teaches medical devices coated with either a butyl ester cyanoacrylate polymer or a methylene malonic acid ester where the polymer is applied to the medical device by dipping the medical device in a solution of the polymer. '352 also discloses that proteins and calcium carbonate are applied to the device and that the coating compositions are sterilized.

10. Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine '037 and '352 with the motivation of regulating the pH of an

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environment at a range at which the polymer's in vivo biodegradation occurs at a different rate than it does at physiological pH to provide controlled release.

Furthermore, the application with a sterilized coating composition to a stent by dipping the stent into the sterile solution of polymer with the motivation of avoiding infection in the subject treated with the stent.

Response to Arguments

11. Applicant's arguments filed 3-14-03 have been fully considered but they are not persuasive. Essentially, Applicant argues that '352 does not remedy the deficiencies of '037 furthering that neither reference teaches a coating comprising a polymethylene malonic acid ester. In response, comments *supra*, paragraph 6, are again relied upon. It is further submitted that '352 teaches equivalence between the alkyl cyanoacrylates and methylene malonates (see examples and claim 12). Accordingly, Applicant's comments are not found persuasive.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw
May 27, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600